

REMARKS/ARGUMENTS

In response to the Office Action mailed February 4, 2010 Applicants request reconsideration in view of the following remarks. In this amendment, no claims are amended, no claims have been cancelled without prejudice and no claims have been added so that Claims 1-4 are currently pending. No new matter has been introduced.

Claims 1-4 were rejected as being unpatentable under 35 USC 103 (a) as being obvious over U.S. Patent Publication 2005/166841 to Robida (Robida) in view of U.S. Publication No. 2005/136090 to Falotico et al. (Falotico). This rejection is respectfully traversed.

In order to make a finding of obviousness, an Examiner must (1) determine the scope and content of the prior art, including non-analogous art if it is in the field of endeavor reasonably related to the particular problem to which the claimed invention is directed, (2) ascertain the differences between the claimed invention and the prior art, considering both the prior art and claimed invention as a whole, and (3) resolve the level of ordinary skill in the art at the time of the invention, factoring in the creativity that one of ordinary skill in the art would employ as well as the Examiner's own knowledge and technical expertise.

It is respectfully submitted that the references taken as a whole fail to disclose or suggest all of the claimed limitations. However, before we can address these issues, it is important to clarify certain facts. The Falotico reference is not a 102(e) reference. Section 102(e) states that "the invention was described in (1) an application for patent, published under section 122(b), by another filed..." In this case, the inventive identity appears to be identical, and thus not "by another." In addition, Falotico does not

appear to qualify as prior art under any section of 102 and thus cannot be utilized as a secondary reference under the 103(a) rejection. Even if it were a 102(e) reference, 103(c) cannot be used as the Examiner suggested because 103(c) requires "Subject matter developed by another person..." which once again cannot be done. Accordingly, Robida stands alone as the single reference.

Robida discloses a clamping fixture for spray coating stent. Robida discloses there is a need for a device for holding a stent during a coating operation that supports the stent against the forces of the coating operation and that does not inhibit the coating process. Robida also discloses that stents may be coated with drug-loaded polymer coatings. Robida discloses a laundry list of therapeutic agents including the anti-proliferative rapamycin and cladribine. Robida also discloses that any of the agents may be combined. Robida fails to disclose or even suggest a combination of two agents and two polymers used in the same coating system. The present invention claims a medical device comprising an implantable structure, a basecoat matrix, including a combination of rapamycin and cladribine, in therapeutic dosages, incorporated in a first polymeric material comprising polyvinylidene fluoride-co-hexafluoropropylene with a weight ratio of 60 weight percent vinylidene fluoride to 40 weight percent hexafluoropropylene, the basecoat matrix being affixed to the surface of the implantable medical device, the concentration of cladribine being in the range from about fifty-six nano molar to about nine-hundred nano molar, and a topcoat, including a second polymeric material comprising poly(n-butylmethacrylate), affixed to the basecoat matrix for controlling the elution rate of the combination of rapamycin and cladribine, wherein the second polymeric material is incompatible with the first polymeric material, thereby creating both a physical and chemical barrier to the elution of the rapamycin and cladribine. Robida fails to disclose or suggest the claimed subject matter. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Applicant would be grateful for the opportunity to conduct a telephonic or in-person interview if the Examiner believes it would be helpful in disposing of the present case.

Respectfully submitted,

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